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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,504	08/21/2001	Toshio Ota	084335/0133	2313

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,504	OTA ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-9,11,15 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10, 12-14, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed November 25, 2002. Currently, claims 1-19 are pending. Claims 7-9, 11, 15, 17-19 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-6, 10, 12-14 and 16 in Paper No. 13 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. This application claims priority to PCT/JP99/04549, filed August 24, 1999. The application also claims priority to Japanese foreign document 10/262941, filed September 17, 1998.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 10, 12-14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Roeder (Nucleic Acids Research, Vol. 26, No. 14, pages 3451-3452, July 1998).

It is noted that Claims 10, 12-14, 16 are directed to Product-by-Process Claims.

> As provided in the MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Roeder teaches solid-phase cDNA library construction such that cDNA is immobilized via a biotin residue to streptavidin coupled magnetic beads (abstract). Roeder teaches isolating mRNA using a modified 5'-biotinylated oligodT(25) primer bound to streptavidin coated magnetic beads. The mRNA is bound to the solid phase via the oligodT-primer. As seen in Figure 1, the third step is second-strand cDNA synthesis accomplished by Rnase H and DNA-polymerase. Roeder also teaches random priming with T(25)G/A/C- 3' from total mRNA which provides cDNA which encodes arbitrary amino acids within the same reading frame (page 3451, col. 2, lines 1-12)(limitations of Claim 4). Roeder teaches that "to show the usefulness of this approach, I randomly chose 10 clones" from libraries and sequenced them from their 5' end (page3452). Moreover, Roder

teaches that the random-primed cDNA revealed a start codon followed by an uninterrupted open reading frame (col. 3452)(limitations of Claim 5-6). With respect to Claim 16, the original mRNA constitutes an mRNA library as required by the claims.

Therefore, the cDNA library is immobilized. The 5' side of the sense strand is immobilized to the bead through hybridization to the antisense strand which is biotinylated to the support. Therefore, since Roeder teaches every limitation of the claims, Roeder anticipates the claimed invention.

5. Claims 1-2, 5-6, 10, 12-14, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Belyavsky et al (US Pat. 5,814,445, September 29, 1998).

It is noted that Claims 10, 12-14, 16 are directed to Product-by-Process Claims.

> As provided in the MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Belvavsky et al. (herein referred to as Belvavsky) teaches a method of identifying and cloning differentially expressed mRNAs which involves capturing the nucleic acids via a microbead. As seen in Figure 6, first chain of cDNA is synthesized from RNA, a biotinylated primer is used to synthesize a second chain of cDNA, and the cDNA fragments are immobilized at the 5' terminus of the sense strand of the cDNA. Belvavsky teaches that after one synthesizes the first chain with the aid of a set of random hexamer primers, synthesis of the second chain with the aid of primer 1 containing a biotin group at

the 5' end, immobilizes the cDNAs in streptavidin microgranules (col. 6-7). Thus, since Belvavsky teaches every limitation of the claims, Belvavsky anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6, 10, 12-14, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minter (US Pat. 5,922,574, July 1999) in view of Dynal Catalog (Biomagnetic Techniques in Molecular Biology, pages 43-50, 1998).

It is noted that Claims 10, 12-14, 16 are directed to Product-by-Process Claims.

> As provided in the MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Minter teaches a method of producing copies of a nucleic acid using immobilized oligonucleotides. As seen in Figure 2A-B, a double stranded nucleic acid is denatured, trapped, extended with a primer, denatured, rehybridized and extended again. The figure illustrates on the right hand side using a primer of CCCC to capture the antisense strand, Z, and extending such that the resulting sense strand is immobilized at the 5' end. Minter teaches that the preferable solid support system is a particulate system and the oligonucleotides are immobilized on the particles (col. 2, lines 35-40).

Minter does not specifically state that the depicted nucleic acid is an mRNA, cDNA hybrid, however, the figure clearly provides a poly a tail on the first sense strand and a poly T tail at the 5' end of the antisense strand such that it appears that a cDNA is exemplified.

Moreover, Dynal specifically teaches generating a reusable solid-phase cDNA library on a particle, namely beads. Dynal teaches construction of immobilized cDNA libraries for multiple RT-PCR amplifications. Dynal teaches using Dynabeads to capture mRNA to synthesized first-strand cDNA. Dynal teaches that the advantages of using dynabeads for immobilized cDNA libraries includes creating a covalently linked first-strand cDNA. The construction of a reusable solid-phase cDNA library allows multiple downstream amplification of specific transcripts. Dynal outlines several additional

advantages for using Dynabeads (page 45). As seen in Figure 10, mRNA is used to generate a reusable solid-phase cDNA library and downstream amplification products.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified the method of Minter to specifically encompass making full length immobilized cDNA libraries as taught by Dynal. The ordinary artisan would have clearly recognized that solid phase cDNA libraries were advantageous to allow generation of a reusable solid-phase cDNA library. Dynal teaches numerous reasons a reusable solid-phase cDNA library is desirable including convenient cDNA storage and availability for studies of gene expression, for example (page 45-46). Dynal teaches that construction of a cDNA library from tiny amount of mRNA has been successful since by synthesizing an immobilized cDNA library on Dynabeads all manipulations can be carried out in one tube. The method of Minter immobilizes both strands of the cDNA at the 5' end such that both the sense and the antisense strands are immobilized at the 5' end.

8. Claims 1-6, 10, 12-14, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Pat. 5,837,468, November 17, 1998) in view of Dynal Catalog (Biomagnetic Techniques in Molecular Biology, pages 43-50, 1998).

It is noted that Claims 10, 12-14, 16 are directed to Product-by-Process Claims.

> As provided in the MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Wang et al. (herein referred to as Wang) teaches a method of generating PCR-based cDNA libraries with anchored ends and isolating the ends of a cDNA clone. As seen in Figure 1, a simple PCR based method for generating a cDNA library with anchored ends is presented. The mRNA is reverse transcribed using a polyTV primer and Rtase to generate a first strand of cDNA. The cDNA is then dC-tailed and the cDNA is further amplified using a poly TV and Poly GH primer for amplification such that a full length cDNA library is generated with anchored ends. A cDNA library is produced that contains full-length cDNAs, anchored at both ends by known sequences, "anchored-end cDNA library" (col. 7, lines 28-32). As seen in Figure 1, the library contains specific additional adaptor sequences 5' and 3' of the poly T and polG sequences. Wang teaches that the driver cDNA library may be tagged using biotin-dCTP such that the subtractive hybridization step may be performed.

Wang does not specifically teach capturing the full length cDNAs .

However, Dynal specifically teaches generating a reusable solid-phase cDNA library. Dynal teaches construction of immobilized cDNA libraries for multiple RT-PCR amplifications. Dynal teaches using Dynabeads to capture mRNA to synthesized first-strand cDNA. Dynal teaches that the advantages of using Dynabeads for immobilized cDNA libraries includes creating a covalently linked first-strand cDNA. The construction of a reusable solid-phase cDNA library allows multiple downstream amplification of specific transcripts. Dynal outlines several additional advantages for using Dynabeads (page 45). As seen in Figure 10, mRNA is used to generate a reusable solid-phase cDNA library and downstream amplification products. Dynal teaches capturing using a polyT primer.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified the method of Wang to specifically encompass capturing full length immobilized cDNA libraries using polyT or polyG primers as taught by Dynal. The ordinary artisan would have clearly recognized that solid phase cDNA libraries were advantageous to allow generation of a reusable solid-phase cDNA library. Dynal teaches numerous reasons a reusable solid-phase cDNA library is desirable including convenient cDNA storage and availability for studies of gene expression, for example (page 45-46). The method of Wang teaches that the polyTV and polyGV is used for PCR amplification, therefore, the ordinary artisan would have been motivated to have immobilized the poly TV and polyGV primers to a solid support to enable creating a solid-phase cDNA library.

Conclusion

9. No claims allowable over the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
February 3, 2003

B.J. FORMAN
PATENT EXAMINER